UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, STATE OF CALIFORIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF GEORGIA, STATE OF FLORIDA, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF LOUISIANA, STATE OF MICHIGAN, COMMONWEALTH OF MASSACHUSETTS, and STATE OF NEW YORK *ex rel.* OMNI HEALTHCARE, INC.,	*	Civil Action No. 21-cv-10950-ADB
Plaintiffs,	*	
v.	*	
EXAGEN, INC., and JOHN DOES 1–10,	*	
Defendants.	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Before the Court are a Motion to Dismiss, [ECF No. 40], filed by Defendant Exagen, Inc. ("Exagen" or "Defendant") and a Motion for Leave to Amend, [ECF No. 51], filed by Relator Omni Healthcare, Inc. ("Omni" or "Relator"). For the reasons that follow, the Court **GRANTS** the Motion to Dismiss with prejudice and **DENIES** the Motion for Leave to Amend.

I. BACKGROUND

A. Factual and Procedural Background

Relator Omni is a multi-specialty medical professional group based in Florida offering a range of medical services at its various locations. [ECF No. 17 ("Amended Complaint" or "Am. Compl.") ¶ 8]. Defendant Exagen develops and sells testing products for patients with "debilitating and chronic autoimmune diseases" under the brand name "AVISE." [Id. ¶ 9].

On June 7, 2021, Omni filed an initial sealed *qui tam* complaint pursuant to the False Claims Act ("FCA") alleging a scheme to induce physicians to make lab-testing referrals in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C § 1320a-7b(b). See [ECF No. 1 ("Complaint" or "Compl.")]. Omni filed an Amended Complaint on August 29, 2022, adding allegations that Exagen's conduct also violated the Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220. See [Am. Compl.]. The Amended Complaint asserts twelve causes of action: Count I alleges a violation of the federal FCA, while Counts II–XII allege violations of state-law analogues to the FCA. See [id. ¶¶ 50 (Count I), 53–85 (Counts II-XII)].

Pursuant to its authority under the FCA, on October 16, 2023, the United States, after investigating the allegations, partially intervened in the case for purposes of entering a settlement. [ECF No. 30 ("Notice of Intervention") at 1 (stating that the government "intervene[s] in part of this action, solely for purposes of settlement," and otherwise "decline[s] to intervene")]; see also 31 U.S.C. § 3730(b)(2), (b)(4). The Government's intervention was limited to "the Covered Conduct, as defined in the Settlement Agreement between the United States and Exagen." [ECF No. 30 at 1; see also id. ("The United State declines to intervene in this action as to any allegations not included in the Covered Conduct . . . .")]. The Settlement Agreement in turn defines "Covered Conduct" as the following:

> Numerous physicians and physician groups ordered Exagen's laboratory tests to assist in the diagnosis of autoimmune conditions (collectively, "the referring physicians"). From June 25, 2014 through June 21, 2021, Exagen paid certain of the referring physicians to complete blood draws for patients pursuant to specimen processing agreements that Exagen had executed with the referring physicians. Exagen also billed Medicare for tests that it performed after receiving orders from the referring physicians to whom it paid the specimen processing fees. On June 25, 2014, HHS-OIG released a Special Fraud Alert: Laboratory Payments to Referring Physicians ("SFA"), which indicated that these arrangements could present a substantial risk of fraud and abuse under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). Exagen terminated the physician referral arrangements by June 21, 2021, and it no longer has any such agreements with referring physicians. This conduct is referred to as the "Covered Conduct." The physician referral arrangements included as part of the Covered Conduct are referenced in Schedule A, attached hereto in redacted form.

[ECF No. 32-1 ("Settlement Agreement") ¶ D]. Schedule A identified payments to fifty-two specified providers across thirteen medical offices between June 25, 2014 and June 21, 2021. [Id. at 14–16].

As per the Settlement Agreement, Exagen agreed to pay $653,143 in restitution to the government, $104,505 of which would be conveyed to Omni as the relator's share. [Settlement Agreement ¶¶ 1–2]. Exagen also agreed to pay $85,000 to Omni in statutory attorneys' fees and costs. [Id. ¶ 3]. As relevant here, the Settlement Agreement contains two release provisions. The United States released Exagen "from any civil or administrative monetary claim the United States has for the Covered Conduct under the common law theories of payment by mistake, unjust enrichment, and fraud." [Id. ¶ 4 (emphasis added)]. In addition, the Settlement Agreement also released Exagen from:

> any and all liability, claims, allegations, demands, actions and causes of action whatsoever in law or equity, that Relator has or could have asserted against Exagen for the Covered Conduct, including but not limited to any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act.

[Id. ¶ 5 (emphases added and citation omitted)]. Notwithstanding these release provisions, the Settlement Agreement specified that "[a]ny liability to the United States (or its agencies) for any conduct other than the Covered Conduct" was reserved. [Id. ¶ 6(d)].

The Settlement Agreement further stipulated the parties' dismissal terms. Specifically, it provided that:

> a. dismissal shall be with prejudice as to the United States and Relator for the Covered Conduct; and
> b. dismissal shall be without prejudice to the United States as to all other claims against.

[Settlement Agreement ¶ 16].

On November 2, 2023, the Court dismissed the case pursuant to the parties' stipulation and the Settlement Agreement. See [ECF No. 33]. In relevant part, the Court ordered that:

> 1. The relator's Amended Complaint and claims against Exagen in this qui tam action are dismissed with prejudice to the United States and the relator as to the Covered Conduct, as that term is defined in the Settlement Agreement;
> 2. Any remaining claims against Exagen contained in the relator's Amended Complaint are dismissed without prejudice as to the United States only; and
> 3. This Court shall retain jurisdiction solely as to the relator's remaining, non-released claims that are outside of the Covered Conduct pursuant to the Settlement Agreement.

[Id. at 2].

Subsequently, on January 22, 2024, Exagen moved to dismiss the non-released claims of the Amended Complaint, meaning any claims in the Amended Complaint that are outside the Covered Conduct. [ECF No. 40]. Exagen first argues that although the Settlement Agreement

"purported to carve out 'any remaining claims against Exagen contained in the relator's Amended Complaint' . . . , in fact, no remaining claims exist" because the only remaining allegations relate solely "to 'specimen processing' payments made by Exagen to physicians that ordered Exagen's tests," i.e., "the precise payments that are identified as the Covered Conduct in the Settlement Agreement." [ECF No. 41 at 7]. In addition, Exagen maintains that (1) "the False Claims Act does not authorize a relator to continue to litigate an action after the DOJ has dismissed the case," (2) Omni failed to plead the elements of a claim under the FCA, including scienter and causation, and (3) Omni did not comply with the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) because it failed to identify specific claims. [Id. at 7–8].

Rather than opposing Exagen's motion, Omni moved for leave to file a Second Amended Complaint, [ECF No. 51-2 ("Proposed Second Amended Complaint" or "Proposed SAC")], containing additional factual allegations derived from the government's investigative report. [ECF No. 51; ECF No. 52 at 7]. Specifically, the Proposed SAC alleges that Exagen's referral scheme extended beyond physician providers to include laboratories and phlebotomists. See [Proposed SAC at ¶¶ 55–87]. These non-physician claims, Omni contends, [ECF No. 52 at 10–11], were contemplated by the Amended Complaint, as it specified that the illicit scheme pertained to "physicians and others," [Am. Compl. ¶ 2 (emphasis added)]. Further, since the Covered Conduct concerns solely physician referrals, Omni asserts it is entitled to bring these other claims under the terms of the Settlement Agreement. [ECF No. 52 at 5–7, 10–11]. Omni additionally argues that the Court should grant leave to amend because (1) its motion was promptly filed after it received the full discovery from the government's investigation; (2) the proposed amendments are not futile; and (3) Exagen would not be prejudiced by the Proposed SAC. [Id. at 8–12].

II. REGULATORY FRAMEWORK

A. The FCA and AKS

The FCA assigns civil liability to any person or entity who "knowingly presents," "causes to be presented," or "conspires to" present "a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A)–(C). Under the statute, a claim "includes direct requests to the [g]overnment for payment as well as reimbursements requests made to the recipients of federal funds under federal benefit programs." Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 579 U.S. 176, 182 (2016). To prevail on an FCA claim, a plaintiff must show that the falseness of the claim was material to the government's payment decision and that it was submitted "knowingly." Guilfoile v. Shields, 913 F.3d 178, 187 (1st Cir. 2019). The FCA defines "knowingly" as having "actual knowledge of the information," "act[ing] in deliberate ignorance of the truth or falsity of the information," or "act[ing] in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

The AKS makes it a criminal offense to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person":

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

Omni Healthcare, Inc. v. MD Spine Sols. LLC, No. 18-cv-12558, 2025 WL 32676, at *4 (D. Mass. Jan. 6, 2025) (alterations in original) (quoting 42 U.S.C. § 1320a-7b(b)(2)). Congress enacted the AKS "to prevent medical providers from making decisions based on improper

financial incentives rather than medical necessity and to ensure that federal health care programs do not bear the costs of such decisions." U.S. ex rel. Banigan v. PharMerica, Inc., 950 F.3d 134, 137 (1st Cir. 2020); Guilfoile, 913 F.3d at 192–93 (explaining the AKS seeks to prevent "the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs"). Thus, "the AKS targets any remunerative scheme through which a person is 'paid "in return for" referrals' to a program under which payments may be made from federal funds." Guilfoile, 913 F.3d at 189 (quoting United States v. Patel, 778 F.3d 607, 618 (7th Cir. 2015)). As relevant for present purposes, "[a] 2010 amendment to the AKS provides that a 'claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].'" United States v. Regeneron Pharms., Inc., 128 F.4th 324, 327 (1st Cir. 2025) (alterations in original) (quoting 42 U.S.C. § 1320a-7b(g)). As such, an FCA claim may be predicated on an AKS violation. Guilfoile, 913 F.3d at 190 ("An AKS violation that results in a federal health care payment is a per se false claim under the FCA.").

III. MOTION TO AMEND

A. Legal Standard

Rule 15(a) permits a party to amend a pleading "with the court's leave" and provides that leave to amend generally should be "freely give[n] . . . when justice so requires." Fed. R. Civ. P. 15(a)(2). Although this standard reflects "a liberal amendment policy," the Court "enjoys significant latitude in deciding whether to grant leave to amend." Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 60–61 (1st Cir. 2018) (citation omitted). A court may deny leave based on "undue delay, bad faith or dilatory motive, . . . undue prejudice to the opposing party . . . [and]

futility of amendment." ACA Fin. Guar. Corp v. Advest, Inc., 512 F.3d 46, 55–56 (1st Cir. 2008) (quoting Forman v. Davis, 371 U.S. 178, 182 (1962)).

B. DISCUSSION

1. Futility

A district court may deny leave to amend "if the proposed amendment would be futile because, as thus amended, the complaint still fails to state a claim." Abraham v. Woods Hole Oceanographic Inst., 553 F.3d 114, 117 (1st Cir. 2009) (citation omitted); see also Rife v. One W. Bank, F.S.B., 873 F.3d 17, 21 (1st Cir. 2017) ("'Futility' means that the complaint, as amended, would fail to state a claim upon which relief could be granted." (citation omitted)). When analyzing whether a proposed amendment would be futile, district courts apply the pleading standards governing dismissal under Rule 12(b)(6). See Amyndas Pharms., S.A. v. Zealand Pharma A/S, 48 F.4th 18, 40 (1st Cir. 2022) (citation omitted). If a proposed amendment "'contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face,' and contains no other fatal defects, the district court abuses its discretion by denying the motion to amend on futility grounds." Id. (second level quotation marks omitted) (first quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); and then citing Abraham, 553 F.3d at 117).

Here, because the essence of an FCA claim is fraud, Rule 9(b)'s heightened pleading requirement, rather than the traditional Rule 8(a) standard, applies. U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 227–28 (1st Cir. 2004), abrogated on other grounds by Allison Engine Co. v. U.S. ex rel. Sanders, 553 U.S. 662 (2008) and Lestage v. Coloplast Corp., 982 F.3d 37 (1st Cir. 2020). An FCA complaint (or, as here, a proposed amended complaint) must state "with particularity" "the circumstances constituting fraud," id. at 226; see also Fed. R.

Civ. P. 9(b), requiring a relator "to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." U.S. ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2013) (citation omitted); see also U. S. ex. rel. Kelly v. Novartis Pharms. Corp., 827 F.3d 5, 13 (1st Cir. 2016) ("The particularity requirement means that a complaint must specify 'the time, place, and content of an alleged false representation.'" (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996))); United States v. Teva Pharms. USA, Inc., 560 F. Supp. 3d 412, 418 (D. Mass. 2021) (applying the heightened Rule 9(b) pleading standard to an FCA claim premised on the AKS). The First Circuit has explained the level of specificity to meet the requirement:

> [D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity.

Karvelas, 360 F.3d at 233. The First Circuit also cautioned that "[t]hese details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint." Id. Nonetheless, "some of this information for at least some of the claims must be [pled] in order to satisfy Rule 9(b)." Id. (citation omitted).

Exagen contends that Omni's proposed amendment is futile on two grounds. First, Exagen argues that Omni's claim is barred under the FCA because the statute does not allow a relator to continue to pursue claims where the government has intervened, settled part of the relator's original allegations, and then dismissed any remaining claims. [ECF No. 53 at 11–14]. Second, Exagen contends that even if the FCA allows a relator to pursue such claims, the Proposed SAC fails to allege facts with sufficient particularity as required by Rule 9(b). [Id. at 15–18].

a. Whether the FCA allows a relator to pursue non-intervened, non-released claims after the government has settled intervened claims

The FCA authorizes private parties like Omni to bring a qui tam action as a relator "in the name of the [g]overnment." 31 U.S.C. § 3730(b)(1). A relator's initial complaint must remain under seal for no less than sixty days, and the relator must serve the complaint, along with "written disclosure of substantially all material evidence and information" in the relator's possession, on the United States. Id. § 3730(b)(2). Before the Court unseals the complaint, the FCA allows the government either to "intervene" or "decline[]" to intervene. Id. § 3730(b)(2), (4). If the government intervenes, it takes on "the primary responsibility for prosecuting" the allegations, although the relator has "the right to continue as a party to the action." Id. § 3730(c)(1). Upon intervention, "the [g]overnment may dismiss the action" over the relator's objection upon appropriate notice to the relator and an opportunity for a hearing. Id. § 3730(c)(2)(A). Alternatively, "the [g]overnment may settle the action."[1] Id. § 3730(c)(2)(B).

Exagen contends that the FCA does not allow relators to prosecute an alleged false claim after the government has intervened and agreed to a settlement. See [ECF No. 53 at 11–12]. Because the government intervened in this case, "entered into a Settlement Agreement, and dismissed the case in its entirety," Exagen maintains that the FCA does not authorize Omni to litigate the case any further. [Id. at 13 (emphasis omitted)]. The question before the Court, therefore, is whether the FCA permits a relator to pursue non-intervened claims after the

[1] The action may be settled over the relator's objection "if the Court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances." Id. § 3730(b)(2)(B).

government has entered into a settlement as to intervened claims. [ECF No. 53 at 11–14]. The Court finds it does.

As a threshold matter, the Court fully understands Exagen's frustration with potentially having to continue to litigate a complaint that it believes it has settled. That said, the Court cannot ignore that the language in the Settlement Agreement specifically resolved only claims related to the physician referral arrangements (the Covered Conduct), and the agreed-upon stipulation expressly provided that claims "outside of the Covered Conduct" were not released pursuant to the Settlement Agreement and were dismissed "without prejudice as to the government only." [Settlement Agreement ¶ D; ECF No. 33]. Moreover, Paragraph 6 of the Settlement Agreement clearly states that "[n]otwithstanding the releases given in Paragraphs 4 [releasing Exagen from claims as to the United States for the Covered Conduct] and 5 [releasing Exagen from claims as to Omni for the Covered Conduct], . . . claims . . . of the United States are specifically reserved and are not released . . . for any conduct other than the Covered Conduct." [Settlement Agreement ¶ 6(d)]. The Settlement Agreement, according to its plain language, therefore, contemplates the possibility that at least the government may bring future claims as to the non-Covered Conduct.

If Exagen had wanted to foreclose this possibility, it had an avenue to do so, that is by not consenting to a settlement that did not include a complete release. Smart v. Gillette Co. Long-Term Disability Plan, 70 F.3d 173, 178 (1st Cir. 1995) ("[C]ontracts containing unambiguous language must be construed according to their plain and natural meaning."); cf. In re P.R. Pub. Fin. Corp., 109 F.4th 37, 50 (1st Cir. 2024) ("[T]he omission of a Valid Claim Requirement in the final documentation was a consequence of the Requisite Bondholders' failure to exercise their right to object."). "There is no obvious reason why the parties could not have structured the

settlement" to cover both Covered and non-Covered Conduct, and "it is likewise difficult to see why it would be entirely unfair to require [Exagen] to live with the consequences of [its] strategic choices." Salvati v. Fireman's Fund Ins. Co., 368 F. Supp. 3d 85, 93 (D. Mass. 2019). It may be that this language was included to facilitate a settlement, with Exagen hoping that nothing more would come of it. Nonetheless, "[l]ike all litigants who settle a case, [Exagen] accepted the risk that post-settlement developments," here, Omni's receipt of additional information regarding the non-Covered Conduct, "might change [its] assessment of how favorable the settlement agreement was." U.S. Sec. & Exch. Comm'n v. Ahmed, No. 15-cv-13042, 2021 WL 916266, at *4 (D. Mass. Mar. 10, 2021); see also United States v. Bank of N.Y., 14 F.3d 756, 759 (2d Cir. 1994) ("When a party makes a deliberate, strategic choice to settle, she cannot be relieved of such a choice merely because her assessment of the consequences was incorrect."). This is all to say that Exagen agreed to a settlement agreement that was expressly restricted to defined Covered Conduct, and the Court finds no persuasive reason to deviate from the parties' consensual resolution.

The Court acknowledges that the Settlement Agreement expressly reserves claims related to the non-Covered Conduct only as to the government, and not Omni.[2] See [Settlement Agreement ¶ 6(d)]. Exagen, however, presents no reason why Omni should not be allowed to

[2] Courts have generally agreed that under the best reading of the statute, "each claim in a multi-claim [FCA] complaint must be treated as if it stood alone." U.S. ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 101–02 (3d Cir. 2000) (Alito, J.). In other words, the "FCA's reference to 'action' may reasonably be read to mean 'claim.'" U.S. ex rel. Schumann v. AstraZeneca Pharm. LP, 769 F.3d 837, 846 (3d Cir. 2014) (citing Merena, 205 F.3d at 101–02). Consequently, "[i]t has long been understood that the government can choose to intervene as to fewer than all of the claims set forth in an FCA case," U.S. ex rel. White v. Mobile Care EMS & Transp., Inc., No. 15-cv-00555, 2021 WL 6064363, at *9 (S.D. Ohio Dec. 21, 2021) (citing cases); see also United States ex rel. Rauch v. Oaktree Med. Ctr., P.C., No. 15-cv-01589, 2020 WL 1065955, at *8 (D.S.C. Mar. 5, 2020).

pursue claims under the FCA on which the government has not intervened.[3] While the statute is silent on this issue, other courts "regularly allow relators to pursue their separate claims after the government's intervention."[4] U.S. ex rel. Ormsby v. Sutter Health, 444 F. Supp. 3d 1010, 1075 (N.D. Cal. 2020); see also U.S. ex rel. Ketroser v. Mayo Found., 729 F.3d 825, 826 (8th Cir. 2013); U.S. ex rel. Barmak v. Sutter Corp., No. 95-cv-07637, 2002 WL 987109, at *2–3 (S.D.N.Y. May 14, 2002). Indeed, courts have allowed the government to intervene in a subset of claims, for purposes of settlement, while preserving a relator's ability to pursue non-settled claims.

In Barmak, for example, the relator alleged that the defendants, sellers of physical therapy devices, had engaged in a Medicare-overpayment scheme involving three components:

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[3] Exagen appears to suggest that the government has in fact intervened on all claims and dismissed the case in its entirety. [ECF No. 53 at 13]. That is not entirely accurate. The government intervened for purposes of the settlement of the Covered Conduct and otherwise declined to intervene. See [ECF No. 33]. The government in fact expressly reserved its right to bring claims as to the non-Covered Conduct, that is claims it did not intervene on. [Settlement Agreement ¶¶ 4, 6(d)]. As such, to the extent Exagen relies on United States, ex rel. Polansky v. Executive Health Resources, Inc., 599 U.S. 419, 423–24 (2023) for the proposition that Omni is forestalled from pursuing non-released claims because the government intervened and subsequently dismissed the case, [ECF No. 53 at 12–14], the Court is not persuaded that such a comparison is apt or indeed based on a correct reading of Polansky. In Polansky, the Supreme Court cemented that the FCA's purpose is to "vindicate the [g]overnment's interests," and as such held that the statute permits the government to dismiss an FCA action over a relator's objection even if the government intervened after the seal period, so long as the government intervened at some point in the litigation. 599 U.S. at 435, 438. In contrast here, the government did not intervene as to the non-released claims, creating a different factual scenario. Polansky underscores the notion that the government is the "real party in interest," but nothing in the opinion appears to foreclose a relator's ability to pursue non-released, non-settled claims. Id. at 425 (citing U.S. ex rel. Eisenstein v. City of New York, 556 U.S. 928, 930 (2009)); see generally id.

[4] Courts also permit relators to amend their operative complaints after the government's partial intervention. See U.S. ex rel. Ormsby v. Sutter Health, 444 F. Supp. 3d 1010, 1075–77 (N.D. Cal. 2020).

(a) waiving co-payments; (b) forging certificates of medical need; and (c) paying kickbacks to hospitals and doctors in exchange for referrals. See 2002 WL 987109, at *1. After an investigation, the government intervened "on the claims covering the waiver of co-payments only." Id. The parties agreed to a settlement whereby the relator would release the defendants "from any and all claims . . . , arising out of, in connection with, or relating in any way, to (a) the Covered Conduct and/or (b) this Stipulation and Order." Id. at *1–2. The agreement defined "Covered Conduct" as "[t]he waiver of copayment [sic] allegation only, covering all claims submitted by [defendant] between January 1, 1992 and June 30, 1998 for Medicare reimbursement under HCPCS E0935 for CPMs." Id. at *2 (first and third alteration added). The agreement "expressly reserve[d] . . . 'any claims the Relator may have against [the defendant] arising out of, in connection with, or relating in any way to: (a) Federal health care program claims submitted by [defendant] prior to January 1, 1992 or after June 30, 1998; (b) Medicaid or other non-Medicare claims submitted by [defendant] between January 1, 1992 and June 30, 1998; and (c) attorneys' fees, costs, and other reasonable expenses.'" Id. (alterations added) (citation omitted). Subsequently, the relator filed a second amended complaint, which defendants moved to dismiss. Id. at * 1. Although the court granted defendants' motion, in part because the amended complaint was based on claims the parties had already settled and did not meet the Rule 9(b) pleading standard, the court did not refute the relator's ability to pursue non-intervened, non-released claims after the parties settled the released claims. See generally id.; id. at *4–5; see also Stipulations and Orders, U.S. ex rel. Barmak v. Sutter Health, No. 95-cv-07637 (S.D.N.Y. July 6, 2001), ECF Nos. 29, 30.

Similarly, at least one court in this district has allowed a relator to pursue non-released claims after the parties settled the government's intervened claims. In Omni Healthcare, Inc. v.

MD Spine Solutions LLC, which involved the same relator as here, the parties entered into a settlement agreement "to resolve some of the claims regarding urine drug tests ('UDTs')." No. 18-cv-12558, 2025 WL 32676, at *2 (D. Mass. Jan. 6, 2025). The relator "retained the right to pursue other [non-settled] claims relating to the 'submission or causing the submission of false claims' for [urinary tract infection ("UTI")] testing" after the government declined to intervene in these non-settled claims. Id. (citation omitted); see also Ex. to Def's Mem. of Law in Support of Mot. to Dismiss ¶ 5, Omni Healthcare, Inc. v. MD Spine Sols. LLC, No. 18-cv-12558 (D. Mass. May 18, 2022), ECF No. 85-1 (releasing defendant from relator's claims concerning the covered conduct, but providing that the relator "retains any and all claims" related to the non-released UTI claims).[5] As here, the government also reserved claims "for any conduct other than the Covered Conduct." Id. ¶ 7(d). Additionally, like the dismissal stipulation in the instant case, the court's order approving the proposed settlement expressly ordered that "it shall retain jurisdiction solely as to (a) the relator's [n]on-[r]eleased [] claims." Order, Omni Healthcare, (No. 18-cv-12558), ECF No. 67; see [ECF No. 33 ("This Court shall retain jurisdiction solely as to the relator's remaining, non-released claims that are outside of the Covered Conduct pursuant to the Settlement."). The relator then proceeded with the non-settled, non-intervened claims. See Omni Healthcare, 2025 WL 32676, at *1.

The Court finds no reason to depart from Omni Healthcare, and Exagen has not offered any case law or other authority to compel a different outcome. The Court thus allows Omni to

[5] Although the Court recognizes that, unlike the instant case, the settlement agreement in Omni Healthcare expressly reserved the relator's right to bring non-released claims, this factual distinction is immaterial. The underlying query—namely, whether a relator can pursue non-intervened claims—persists in both scenarios.

pursue the non-settled, non-intervened claims. That said, to avoid futility, the proposed amendments still must satisfy the requirements of Rules 9(b) and 15, the issue the Court turns to next.

b. Whether Omni's proposed amendment satisfies the special pleading requirements of Rule 9(b)

The crux of the Proposed SAC is that Exagen's illicit referral scheme went beyond physicians to include various independent contractors, specifically, phlebotomists and laboratories unaffiliated with referring physicians. [Proposed SAC ¶¶ 55–87]. The operative Amended Complaint focuses on Exagen's referral scheme to the extent that it involved physicians and references other entities only in passing. See [Am. Compl. ¶ 2 ("Exagen offers cash renumeration to physicians and others in order to induce them to refer patients for laboratory testing related to various health issues."[6] (emphasis added)); cf. id. ¶ 1 ("Relator asserts Exagen is providing illegal financial inducements to physicians in exchange for patient referrals for laboratory testing.")]. The factual additions of the Proposed SAC pertain to Exagen's purported illicit referral scheme with non-physician entities, alleging that between 2013 and 2021, Exagen entered into specimen processing agreements ("SPAs") with independent laboratories and phlebotomists. [Proposed SAC ¶¶ 55–87]. Omni alleges that these SPAs disguised illicit referral fees as reimbursements for the collection and processing of blood specimens. [Id. ¶¶ 55–64].

[6] In paragraph 1 of the Amended Complaint, Omni refers solely to purported financial inducements "to physicians," and no other entities. [Am. Compl. ¶ 1].

"Certain legal principles come into play when an FCA claim is premised on an underlying AKS violation."[7] Omni Healthcare, 2025 WL 32676, at *4. First, although Omni need not prove that "compliance with the AKS was material to the government's decision to pay any specific claim," Guilfoile, 913 F.3d at 190, it must show that "there is a sufficient causal connection between [the] AKS violation and a claim submitted to the federal government." Id. Second, Omni must show that Exagen acted "knowingly and willfully." Omni Healthcare, 2025 WL 32676, at *4 (quoting 31 U.S.C. § 1320a-7b(b)(2)). "Willfully" in the context of an AKS claim means "with knowledge that [the] conduct was unlawful." U.S. ex rel. Langer v. Zimmer Biomet Holdings, Inc., No. 21-cv-11293, 2024 WL 3633536, at *5 (D. Mass. Aug. 2, 2024).

Here, the Court cannot find that the Proposed SAC describes the purported illegal kickback scheme between Exagen and independent laboratories and phlebotomists with sufficient particularity. Omni states that Exagen compensated these contractors between $10 and $25 for collecting and processing each specimen, but Omni does not explain why these reimbursements amounted to kickbacks. [Proposed SAC ¶¶ 56, 57–64]. Nor does the Proposed SAC describe how the alleged kickback scheme with third-party contractors relates to the unlawful physician referrals. Omni vaguely suggests that the purported scheme with independent contractors came about because physicians had "concerns" about the number of referrals they could make for Exagen's tests due to unspecified logistical constraints and that Exagen began entering SPAs with independent contractors to "ensure that it had complete

[7] Although Omni alleges that the purported referral scheme also violated EKRA, in the motion to amend the Amended Complaint and the Proposed SAC Omni "frames its arguments [primarily] in terms of the AKS." Omni Healthcare, 2025 WL 32676, at *7 n.3. As such, the Court proceeds under the assumption that an EKRA violation does not require a different analysis than the AKS allegations.

control over the process from test referrals to patient drawings to test delivery."[8] [Id. ¶¶ 56, 57–64]. Omni also asserts that Exagen employed various marketing practices, including educating its employees on billing requirements for laboratory testing and training its sales representatives on how to target regional labs[9] in order to get "additional physician access" in furtherance of increasing test utilization. [Id. ¶¶ 66–85]. These allegations, however, do not explain the purported illegal scheme with sufficient clarity or articulate "the 'who, what, when, where, and how' of the alleged fraud." Takeda Pharm., 737 F.3d at 123 (internal citation omitted); Novartis Pharms., 827 F.3d at 13 (quoting Doyle, 103 F.3d at 194). Instead, Omni states in largely conclusory fashion that "[w]ith the obvious success of the illicit referral scheme with physicians, Exagen was able to broadly implement the scheme to include all manner of independent contractors related to specimen collection and payment of 'referral fees' relying upon volume and value-based referrals." [Proposed SAC ¶ 86; see also id. ¶ 65 ("In a January 2013 email communication . . . Exagen's Director of marketing at the time, explained that the reason a doctor was having a 'slow-down in ordering' was that the doctor did not have an inhouse phlebotomist. Exagen induced the physicians to encourage in-house phlebotomists to contract with Exagen in an attempt to hide their scheme.")]. "Conclusory allegations and references to 'plans and schemes' are not sufficient" to plead fraud. Novartis Pharms., 827 F.3d at 13 (quoting Hayduk v. Lanna, 775 F.2d 441, 444 (1st Cir. 1985)); Takeda Pharm., 737 F.3d at 124 (with

[8] The Proposed SAC does not specify the nature of these concerns beyond stating they were "due to ease of access and other logistical factors." [Proposed SAC ¶ 56].

[9] Regional labs are "labs not associated with a hospital system." [Proposed SAC ¶ 77].

regard to FCA liability, "merely alleging facts related to a defendant's alleged misconduct is not enough").[10]

Nor does the Proposed SAC sufficiently identify the "claims" that were unlawfully submitted to the government. The Proposed SAC primarily provides facts about payments Exagen made to third parties, but, other than offering the total number of specimens processed, how much Exagen paid in reimbursement to third parties, and Exagen's revenue between 2017 and 2019, Omni offers little insight into the claims ultimately submitted to Medicare. [Proposed SAC ¶¶ 57–64, 83–85, 88]. At best, Omni refers to a 2018–19 fee schedule showing that one of Exagen's products, AVISE MTX, was overbilled at a reimbursement rate of $70 when the permissible billing amount for Medicare was listed as $ 24.09. [Id. ¶ 83]. Although it comes closer to stating a claim with particularity, this one paragraph alone cannot remedy a complaint that is overall short on the requisite particularity. Describing a scheme in general terms and then alleging that "claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the [g]overnment" is not sufficient. U.S. ex rel. Clausen v. Lab'y Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002) (pertaining to FCA claims). In sum, the Proposed SAC does not satisfy Omni's obligation to "state with particularity" the "circumstances constituting fraud." Karvelas, 360 F.3d at 227–28.

[10] At oral argument, Omni represented that discovery would explore the conduct between Exagen and physicians about the selection of laboratories. [ECF No. 63 at 28:8–20]. Although discovery is designed to define and clarify issues raised in a complaint, the Proposed SAC here offers minimal facts about the nature of Exagen's purported unlawful compensation scheme with independent contractors and as such fails to survive the demands of Rule 9(b). Karvelas, 360 F.3d at 231 (a relator cannot "present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery.").

c. Whether Omni sufficiently pled scienter

Although a party "must state with particularly the circumstances constituting fraud . . . , [m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." U.S. ex rel. Carbon v. Care New Eng. Health Sys., 567 F. Supp. 3d 355, 359 (D.R.I. 2021) (quoting Fed. R. Civ. P. 9(b)). In order establish that Exagen acted knowingly and willfully, Omni "must allege that [Exagen] acted with knowledge that its conduct was unlawful." Zimmer Biomet Holdings, 2024 WL 3633536, at *5; U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145, 157 (2d Cir. 2024), cert. denied, No. 23-1293, 2024 WL 4426646 (U.S. Oct. 7, 2024) ("A person may be criminally liable under the AKS without knowing of that statute or having a specific intent to violate it, provided that the person acts with knowledge that her conduct is, in some way, unlawful.").

The Proposed SAC remains largely silent on Exagen's scienter. Instead, Omni relies primarily on conclusory statements as to how Exagen employed its industry knowledge to implement the purported scheme. See, e.g., [Proposed SAC ¶ 72 ("Exagen uses [its] specialized knowledge of managed markets to train [its] sales representatives to draw phlebotomists and labs into the fold of [its] illegal referral scheme.")]; [id. ¶ 73 ("For example, Exagen developed a 'Market Development Manager Training' presentation that clearly showcases Exagen's intimate knowledge of the healthcare insurance landscape and how it perverted that knowledge to concoct this [kickback] scheme.")]; [id. ¶ 75 ("It is with [] specialized knowledge [of managed markets] that Exagen's strategy was able to target providers to push their tests to increase their bottom line and disregarded the laws against illegal referrals for payment.")]; [id. ¶ 76 ("Exagen's training materials confirm that Exagen knew that to get to the client bill, sales represented needed to 'remove barriers for access,' 'increase Exagen test utilization,' and 'shorten collection process,'

to ultimately 'increase company revenue.'")]. From these statements alone, however, the Court cannot infer that Exagen acted "knowingly and willfully." Teva Pharms., 560 F. Supp. 3d at 418 ("Threadbare recitals of legal elements which are supported by mere conclusory statements do not suffice to state a cause of action."). Similarly, in passing, Omni states that "[i]ncluded in Exagen's analysis and strategy was information . . . [on] 'providing patient access to Exagen testing where currently prohibited.'" [Id. ¶ 68]. Such a fleeting reference does not adequately allege scienter. United States v. Valley Campus Pharmacy, Inc., No. 16-cv-04777, 2021 WL 5406148, at *3 (C.D. Cal. Oct. 12, 2021), aff'd sub nom. Gharibian ex rel. U.S. v. Valley Campus Pharmacy, Inc., No. 21-56253, 2023 WL 195514 (9th Cir. Jan. 17, 2023) (finding that although defendants had the intent to induce referrals, the relator "never alleges, even generally, that [d]efendants knew that their offer . . . was unlawful," and could therefore not prevail on scienter); but see Teva Pharms., 560 F. Supp. 3d at 421–22 (finding that government sufficiently alleged that defendant knew that its conduct was prohibited by federal law in part because the complaint referenced a presentation warning of the risks associated with the specific conduct). Accordingly, the Court cannot find that Omni adequately pled facts from which the Court could conclude that Exagen acted with the prerequisite intent as to the non-physician entities.

d. Whether Omni sufficiently pled causation

The Proposed SAC falls similarly short on pleading causation. The First Circuit recently held that in order to prevail on causation, a plaintiff must "show that an illicit kickback was the but-for cause of a submitted claim."[11] Regeneron Pharms., 128 F.4th at 336 (emphasis added);

[11] Regeneron resolved a split in this Circuit as to the appropriate causation standard to be applied in an AKS-based FCA claim in light of a 2010 amendment to the AKS. Specifically, the amendment provided that "a claim [for payment by a federal healthcare program] that includes

see also U.S. ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 835 (8th Cir. 2022) (requiring a plaintiff to establish "that the defendants would not have included particular 'items or services' [in claims for payment] absent the illegal kickbacks." (quoting 42 U.S.C. § 1320a-7b(g))). Here, after carefully reviewing the Proposed SAC, the Court cannot find that Omni has sufficiently alleged that the purported kickback scheme was the but-for cause of third-party contractors' use of Exagen's tests. Rather, the Proposed SAC largely describes the purported kickback scheme and then seemingly asks the Court to infer that the scheme led to the use of Exagen's tests. Accordingly, Omni fails to adequately plead causation.

In sum, the Court concludes that Omni's proposed amendments are futile. Accordingly, it need not go further, and the motion to amend as to the federal claims is **DENIED**.

e. State Law Claims

The Proposed SAC, like the operative Amended Complaint, asserts that because "State FCAs are modeled after the Federal FCA, and contain provisions similar to the [federal provisions]," Exagen's purported scheme also violates various state statutes.[12] [Proposed SAC

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items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(g)); 31 U.S.C. §§ 3729–33.

[12] These include: Cal. Gov't. Code § 12650 et seq. (West 2013); Colorado Medicaid False Claims Act, Col. Rev. Stat. 25.5-4-303.5 through 25.5-4-310 (West 2010); Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 et seq. (2017); Florida False Claims Act, Fla. Stat. § 68.081–68.09 (2007); Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq. (2007); Illinois Whistleblower Reward & Protection Act, 740 Ill. Comp. Stat. § 175/1 et seq. (2011); Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5-1 et seq. (2005); Louisiana Qui Tam Action Act, La. R.S. § 46:437.1 et seq. (1997); Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5 et seq. (2000); Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 et seq. (1977); and New York False Claims Act, NY State Fin. Law § 187 et seq (McKinney 2010). [Proposed SAC ¶ 9]. The same state law violations are alleged in the operative Amended Complaint. [Am. Compl. ¶¶ 53–85].

¶ 24]. To the extent that the state laws' requirements diverge from federal law, and, consequently, the analysis supra, Omni has not identified any such differences. See generally [Proposed SAC]; U.S. ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 357 (D. Mass. 2011) ("In order to satisfy Rule 9(b), [defendant] must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings."). Omni further fails to plead that any claims were actually submitted to the respective health care programs. Accordingly, Omni cannot prevail on its state law claims and its motion to amend is **DENIED**.

C. Motion to Dismiss for Failure to State a Claim

Because the Court finds that the Proposed SAC, which offered additional details as to Exagen's purported unlawful compensation scheme with "other," non-physician entities, fails to state a claim under the FCA, it need not consider Omni's operative Amended Complaint. Exagen's motion to dismiss is thus **GRANTED** with prejudice.

IV. CONCLUSION

For the reasons set forth above, the Court **GRANTS** the Motion to Dismiss, with prejudice, and **DENIES** the Motion for Leave to Amend.

SO ORDERED.

March 31, 2025

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE